UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,929	10/15/2003	Christopher H. Porter	355492-4151	4569

38706 7590 08/25/2005

FOLEY & LARDNER LLP
1530 PAGE MILL ROAD
PALO ALTO, CA 94304

EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/686,929	PORTER ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-31 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESTRICTION INTO GROUPS

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 4-16, 19-25, and 31, drawn to a composition and kit comprising a (a) non-reactive biocompatible substance, (b) a rheological modifier, and (c) a biocompatible liquid as set forth in independent claim 1, classified in class 424, subclass 1.11+.

II. Claims 2, 6-18, 21-25, and 31, drawn to a composition and kit comprising (a) a non-reactive biocompatible substance, (b) a rheological modifier, and (c) a contrast agent as set forth in independent claim 2, classified in class 424, subclass 9.3.

III. Claims 3-25 and 31, drawn to a composition and kit comprising (a) a non-reactive biocompatible substance, (b) a rheological modifier, (c) a biocompatible liquid, and (d) a contrast agent as set forth in independent claim 3, classified in class 424, subclass 9.3+.

IV. Claims 1 and 26, drawn to a method of site specific delivery of a composition of the composition of Group I, classified in class 424, subclass 9.1.

V. Claims 1 and 26, drawn to a method of site specific delivery of a composition of the composition of Group II, classified in class 424, subclass 9.1.

VI. Claims 1 and 26, drawn to a method of site specific delivery of a composition of the composition of Group III, classified in class 424, subclass 9.1.

VII. Claims 1 and 27, drawn to a method of embolizing a vascular site using the composition of Group I, classified in class 424, subclass 9.1.

VIII. Claims 2 and 27, drawn to a method of embolizing a vascular site using the composition of Group II, classified in class 424, subclass 9.1.

IX. Claims 3 and 27, drawn to a method of embolizing a vascular site using the composition of Group III, classified in class 424, subclass 9.1.

X. Claims 1, 28, and 29, drawn to a method of bulking tissue via a delivery device using the composition of Group I, classified in class 424, subclass 9.1.

XI. Claims 2, 28, and 29, drawn to a method of bulking tissue via a delivery device using the composition of Group II, classified in class 424, subclass 9.1.

XII. Claims 3, 28, and 29, drawn to a method of bulking tissue via a delivery device using the composition of Group III, classified in class 424, subclass 9.1.

XIII. Claims 1, 21, 24, and 30, drawn to a method of delivery a composition comprising a medicament and the composition of Group I, classified in class 424, subclass 9.1.

XIV. Claims 1, 21, 24, and 30, drawn to a method of delivery of a composition comprising a medicament and the composition of Group II, classified in class 424, subclass 9.1.

XV. Claims 1, 21, 24, and 30, drawn to a method of delivery of a composition comprising a medicament and the composition of Group III, classified in class 424, subclass 9.1.

Note: Claims appearing in more than one group will only be examined to the extent that they read on the elected invention.

2. Groups (I and IV), (I and VII), (I and X), (I and XIII), (II and V), (II and VIII), (II and XI), (II and XIV), (III and VI), (III and IX), (III and XII), and (III and XV) are related as product and process and use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using the product (MPEP 806.05(h)). In the instant case, the distinct products of Groups I - III may be used in their respective methods of Groups IV - XV. Thus, each of the inventions is directed to products having distinct characteristics and the components necessary for each composition is different. For example, one composition requires a non-reactive biocompatible substance, a rheological modifier, and a biocompatible liquid while another requires a non-reactive biocompatible substance, a rheological modifier, a biocompatible liquid, and a contrast agent. As a result, prior art cited against one invention would neither anticipate nor render obvious another group since the presence of the additional (or absence) of other components would not be anticipated or obvious. Hence, a separate search for each invention is necessary since the limitations necessary for each group is different even though some of the inventions may classify in the same area.

3. The inventions are distinct from each other for the reasons set forth above. Hence, since these inventions are distinct and have acquired a separate

status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

REJOINDER PARAGRAPH

4. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b),"

1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

ELECTION OF SPECIES

5. Claims 1-31 are generic to a plurality of disclosed patentably distinct species comprising compositions and uses thereof as set forth in claims 1, 2, 3, and 26-30. The compositions comprise a non-reactive biocompatible substance, a rheological modifier, and optionally, a biocompatible liquid, a contrast agent, and delivery device. Applicant is required under 35 U.S.C. 121 to *elect a single disclosed species for search purposes from within the elected group above*, even though this requirement is traversed.

Note: The Examiner respectfully requests that the Applicant identify each of the following, if appropriate for the elected group above: a specific non-reactive biocompatible substance, a specific rheological modifier, a specific contrast agent, a specific biocompatible liquid, a specific delivery device, a thickening agent, a plasticizer, a radioactive agent, a surfactant, a specific medicament, bulking tissue deliver site, and biocompatible solvent.

6. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Due to the complexity of the restriction requirement, a telephone call was not made to request an oral election to the above restriction requirement.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. L. Jones
Primary Examiner
Art Unit 1618

August 22, 2005